

5 September 2019

Novartis was saddened to learn of the patient, who is suffering from diffuse large B-cell lymphoma (DLBCL), an aggressive form of non-Hodgkin's lymphoma.

We understand that situations like this are very difficult. We are committed to working alongside other stakeholders to facilitate equal access for new therapies, which may provide hope for patients.

Kymriah is the first CAR-T therapy to be approved by the Therapeutic Goods Administration for use in Australia. The Australian Government already has approved Kymriah funding for eligible children and young adults with Acute Lymphoblastic Leukaemia (called pALL), but public funding for adult DLBCL patients is still under assessment. The Government's decision on funding will make it clear whether this innovative, individualised therapy will become available to all eligible Australian patients.

While we await the outcome of the government's assessment, there is an ongoing clinical trial program for DLBCL patients in Australia which has a specific criteria for limited eligible patients. Novartis has been in contact with the patient's treating doctors to understand if the patient may be eligible for any of the ongoing Novartis clinical trial programs.

We have also discussed with the treating doctors other potential treatment pathways which may be available, including government programs such as the Medical Treatment Overseas Program (MTOP) and clinical trial programs from other manufacturers. Unfortunately, it is not possible to provide compassionate access for this type of emerging therapy at this stage due to its complexities.

Medicines Australia, the pharmaceutical industry body, has also asked the Government to work with them in developing appropriate ways for creating timely access to these emerging therapies.

CAR-T therapies are cutting-edge technologies and Novartis continues to work with the Government to address their questions about the funding assessment of Kymriah in DLBCL adult patients.

Across the world, Novartis has already collaborated to reach reimbursement to enable access for patients in 15 countries including the United States, England, Canada and Japan.